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| 09/785,514 | 02/16/2001 | Jian-Bing Fan | A-68970-1/DJB/RMS/DCF | 5362 |

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/14/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/785,514

Applicant(s)

FAN ET AL.

Examiner

Arun Chakrabarti

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s): _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*

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DETAILED ACTION

Specification

1. Claims 14 and 23 have been amended and new claims 27-29 have been added.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

3. Claims 14-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,355,431 B1.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-30 of U.S. Patent No. 6,355,431 B1 clearly teach the instant claimed method of genotyping comprising:

- a) providing an array composition comprising:

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I) a substrate with a surface comprising discrete sites; and

ii) a population of microspheres comprising at least a first and a second subpopulation, wherein the microspheres of each subpopulation each comprise a plurality of different target analytes attached to the microspheres with first and second attachment moieties, respectively (as the attachment moieties are different, the target analytes are inherently different in order to attach to the microspheres);

wherein the microspheres are randomly distributed on the surface;

b) contacting the array composition with a first set of extension probes that hybridize with at least the first target sequence adjacent to a first detection position to form an extension complex;

c) contacting the extension complex with a composition comprising:

I) at least a first nucleotide;

ii) polymerase;

wherein the polymerase extends a first extension probe with the first nucleotide when the first nucleotide is complementary to the first detection position of the first target sequence; and

d) detecting the presence of a first nucleotide and also a method further comprising adding a ligase to form a ligation complex (Claim 6).

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Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 14-29 are rejected under 35 U.S.C. 102 (e) as being anticipated by Chee et al. (PCT International Application Number: WO 99/67641) (December 29, 1999).

Chee et al teach a method comprising:

a) providing an array composition (Claims 1-18) comprising:

I) a substrate with a surface comprising discrete sites (Claims 1, 8, 13-15);

and

ii) a population of microspheres comprising at least a first and a second subpopulation, wherein the microspheres of each subpopulation each comprise a plurality of different target analytes (page 29, lines 1-12 and page 31, line 12 to page 32, line 18);

wherein the microspheres are randomly distributed on the surface (Claims 1-18));

b) contacting the array composition with a first set of readout probes (page 28, lines 11-21);

c) detecting the presence of a first target analyte (page 25, line 34 to page 27, line 5);

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d) contacting the array composition with a second set of readout probes (page 25, line 34 to page 27, line 5));

e) detecting the presence of a second target analyte (page 25, line 34 to page 27, line 5), wherein the two sets of probes comprise two sets of labels.

Chee et al teach a method further comprising detecting the first label as an indication of the presence of the first target analyte (page 25, line 34 to page 27, line 5).

Chee et al teach a method, wherein the first and second target sources are first and second patients (Page 32, lines 1-18).

Chee et al inherently teach a method of genotyping comprising:

a) providing an array composition (Claims 1-2 and 13-14) comprising:

i) a substrate with a surface comprising discrete sites (Claims 1-2 and 13-14); and

ii) a population of microspheres comprising at least a first and a second subpopulation, wherein the microspheres of each subpopulation each comprise a plurality of different target analytes attached to the microspheres with first and second attachment moieties, respectively (Claims 1-2 and 13-14);

wherein the microspheres are randomly distributed on the surface (Claims 1-2 and 13-14);

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b) contacting the array composition with a first set of extension probes that hybridize with at least the first target sequence adjacent to a first detection position to form an extension complex (Page 26, lines 19-27);

c) contacting the extension complex with a composition comprising:

I) at least a first nucleotide (page 27, lines 7-9);

ii) polymerase (page 27, lines 9-11);

wherein the polymerase extends a first extension probe with the first nucleotide when the first nucleotide is complementary to the first detection position of the first target sequence (page 27, lines 9-11); and

d) detecting the presence of a first nucleotide (page 29, lines 1-12).

Chee et al inherently teach a method, wherein the first nucleotide comprises a label (page 25, lines 4-23 and page 29, line 34 to page 30, line 9).

Chee et al inherently teach a method of determining the identification of a nucleotide at a detection position in at least a first target sequence comprising:

a) providing an array composition (Claims 13-14) comprising:

I) a substrate with a surface comprising discrete sites (Claims 13-14); and

ii) a population of microspheres comprising at least a first and a second subpopulation, wherein the microspheres of each subpopulation each comprise a plurality of different target analytes (Claims 13-14);

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b) forming a first hybridization complex between the target sequence and at least a first readout probe (page 26, lines 19-27);

c) determining the nucleotide at the detection position (Claims 13-14 and page 19, line 33 to page 20, line 8).

Chee et al teach a method further comprising adding a ligase to form a ligation complex (Page 27, lines 11-12).

Chee et al teach a method, wherein the substrate is a fiber optic bundle (page 28, lines 26-35).

Chee et al teach a method, wherein the substrate is glass or plastic (page 7, lines 30-32).

Chee et al teach a method further comprising contacting the microspheres with decoder binding ligands, wherein the microspheres of each subpopulation comprises an identifier binding ligand that will bind a decoder binding ligand for identification and elucidation of the target analyte (page 26, line 29 to page 27, line 20).

Response to Amendment

6. In response to amendment, previous 102(e) rejection is withdrawn. However, double patenting rejection is maintained and a new 102(a) rejection have been included.

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Response to Arguments

7. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. Any inquiry of a general nature or

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relating to the status of this application should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located In Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published In the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Chakrabarti
Patent Examiner
Art Unit 1634

August 2, 2002

S. Zomer